UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,994	02/20/2004	Ellis L. Reinherz	1062.2002-004	4354

21005 7590 06/08/2006

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	10/783,994	REINHERZ ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-8, 10-12 drawn to isolated nucleic acid comprising SEQ ID NO:1 and fragments thereof; complement of SEQ ID NO:1 and fragments thereof; nucleic acid that encodes SEQ ID NO:2; nucleic acids and probes that hybridize thereto under high stringency conditions; vectors or plasmids that comprise said nucleic acids; host cells comprising said nucleic acids; classified in class 536, subclass 23.1.

Group II. Claims 9, 13, & 14, drawn to an isolated polypeptide sequence comprising SEQ ID NO: 2 or functional portion thereof and fusion protein thereof; amino acid sequence encoded by SEQ ID NO:1 and fusion protein thereof; methods for preparing a polypeptide encoded by isolated nucleic acid sequence of Group I, classified in class 435, subclass 69.5. and class 435, subclass 183.

Group III. Claims 15-17, drawn to polyclonal and monoclonal antibodies or antibody fragments that binds to a portion of polypeptide of Group II; method of

using antibody to detect polypeptide, classified in class 530, subclass 387.1.

Group IV. Claims 18 drawn to method of using antibodies to detect polypeptide, classified in class 530, subclass 387.1.

Group V. Claims 20-24, drawn to a methods for identifying protein-interaction partners of polypeptide of group II; methods of identifying agents that alter activity of isolated polypeptide of group II, classified in class 435, subclass 7.1.

Group VI. Claims 25-28, and 30, drawn to a non-human transgenic animal comprising polypeptide of group II; method of identifying an agent that alters activity of polypeptide molecule of Group II, using transgenic animal; methods of identifying gene targets of Group II, using transgenic animal, classified in class 800, subclass 21 and class 800, subclass 3.

Group VII. Claims 31, drawn to cell-based assays for identifying gene targets of Group II, classified in class 435, subclass 6.

Group VIII. Claims 32-38, drawn to methods of treating an individual having a disorder, classified in class 424, subclass 94.1.

Group IX. Claims 1-8, 10-12 drawn to isolated nucleic acid comprising SEQ ID NO:3 and fragment thereof; complement of SEQ ID NO:3 and fragment thereof; nucleic acid that encodes SEQ ID NO:4; nucleic acids and probes that hybridize thereto under high stringency conditions; vectors or plasmids that comprise said nucleic acids; host cells comprising said nucleic acids; classified in class 536, subclass 23.1.

Group X. Claims 9 & 13, drawn to an isolated polypeptide sequence comprising SEQ ID NO: 4 or functional portion thereof; amino acid sequence encoded by SEQ ID NO:3; methods for preparing a polypeptide encoded by isolated nucleic acid sequence of Group IX, classified in class 435, subclass 69.5.and class 435, subclass 183.

Group XI. Claims 15-17, drawn to polyclonal and monoclonal antibodies or antibody fragments that binds to a portion of polypeptide of Group X; method of using antibody to detect polypeptide, classified in class 530, subclass 387.1.

Group XII. Claim 19 drawn to method of using antibodies to detect polypeptide, classified in class 530, subclass 387.1.

Group XIII. Claims 20-24, drawn to methods for identifying protein-interaction partners of polypeptide of group X; methods of identifying agents that alter activity of isolated polypeptide of group X, classified in class 435, subclass 7.1

Group XIV Claims 25-30, drawn to a non-human transgenic animal comprising polypeptide of group X; method of identifying an agent that alters activity of polypeptide molecule of Group X, using transgenic animal; methods of identifying gene targets of Group X, using transgenic animal, classified in class 800, subclass 21 and class 800, subclass 3.

Group XV. Claim 31, drawn to cell-based assays for identifying gene targets of Group X, classified in class 435, subclass 6.

Group XVI. Claims 32-38, drawn to methods of treating an individual having a disorder, classified in class 424, subclass 94.1.

2. The inventions are independent or distinct, each from the other because:

Distinctions between Homologous Molecules from different Organisms

There is a group restriction distinction required between the inventions based on human molecules (Groups I-VIII) and those inventions based on mouse molecules

(Groups IX-XIV). The polypeptide and polynucleotide sequences of human and mouse orthologues are structurally distinct chemical compounds and are unrelated to one another. The structural and sequence differences between these groups of inventions are not trivial and are not invention species distinctions. Thus, they are not considered species according to MPEP § 803.2 and are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid and amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

There is a burdensome search associated with identifying inventions related to the human and mouse systems. For example, the search for antibodies immunoreactive against the human peptide would not discover antibodies immunoreactive against the mouse peptide. The differences between the mouse and human systems will make the searching significantly burdensome, so that restriction is required.

Distinctions between Polynucleotides, Polypeptides, and Antibodies

The nucleic acids of Group I and the polypeptides of Group II are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially

different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, the polynucleotide claims do not overlap the scope of the polypeptide claims and vice versa as evidenced by the distinct structures and functions of the claimed inventions. A polynucleotide's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the polynucleotide's function is to encode a protein while a protein's function is variable, and in this case, undefined. Additionally, the polynucleotides and polypeptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the polynucleotides and polypeptides have materially different functions as noted above. Thus, by virtue of the different structures and functions of the inventions of Groups I and II, these related inventions are distinct.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. While Groups I and II can be identically classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Group II, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the nucleotide sequences must be searched in distinct commercial nucleic

acid sequence databases. Thus, Groups I and II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

The polynucleotide of Group I and the antibody of Group III are distinct for the following reasons. The antibody of Group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of Group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotides of Group I will not encode an antibody of Group III, and the antibody of Group III cannot be encoded by a polynucleotides of Group I. Therefore, the antibody and polynucleotide are distinct.

In addition to their distinctness, searching the inventions of Group I and Group III would impose a serious search burden. For example, the antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group I and Group III would impose a serious search burden since a search of the polynucleotide of Group I would not be used to determine the patentability of an antibody of Group III and vice-versa. Because these

inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper.

The polypeptides of Group II and the antibodies of Group III-IV are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, the polypeptide claims do not overlap the scope of the antibody claims and vice versa as evidenced by the distinct structures and functions of the claimed inventions. While both polypeptides and antibodies are structurally related by virtue of their contiguous sequence of amino acids, they are distinct structures based on their three-dimensional structures wherein proteins fold into a variety of structures and antibodies maintain a specific, Y-shape. Polypeptides are functionally distinct from antibodies because antibodies merely recognize a cognate peptide fragment of said polypeptide and polypeptides affect a specific binding to IκBNS. Additionally, the polypeptides and antibodies are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the polypeptides and antibodies have materially different functions as noted above. Thus, by virtue of the different structures and functions of the inventions of Groups II and Groups III-IV, these related inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, the search required is distinct based on the distinct structures as noted above. Thus, to search the proteins with the antibodies would be unduly burdensome. Therefore, Group II is properly restricted from Group III-IV as being distinct and unduly burdensome to be searched together.

Inventions III (antibodies) and IV (methods of using antibodies) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product (antibody) as claimed can be used in a materially different process such as for antibody therapy. Although, Inventions III & IV require restriction because of the distinctions described above and the undue search burden, the applicant is reminded that rejoinder is proper, if the product claims are allowable (see more comprehensive rejoinder statement at end of this document.)

Distinctions between Transgenic animal and other Products/Processes

The non-human transgenic animals and methods using such animals are distinct from other Groups of inventions in this application. This is completely different from the

remaining groups. Although there may seem to be a link between the nucleic acids of Group I and the transgenic animal of Group VI, these are, in fact, unrelated inventions. The nucleic acid of group I is used for methods other than construction of transgenic animals. The transgenic animal of group VI can be used for methods other than screening agents, such as studying gene function. For these reasons, Group VI is distinct from groups I-V and VII-VIII. Despite some common elements (nucleic acid sequences), there would be a search burden for the examiner because the search of these inventions are not co-extensive.

Distinctions between Methods

The remaining methods (Groups V, and VII-VIII) are unrelated inventions, and distinct from each other and groups I-IV &VI. Group V is drawn to methods for identifying protein-interaction partners of a polypeptide. Group VII is drawn to cell-based assays for identifying gene targets. Group VIII is drawn to methods of treating an individual having a disorder. All of these inventions have different method steps that are not included in the other methods. For example, protein-interaction partners requires binding studies (group V), while identifying gene targets includes mRNA procedures (group VII), and treatment of an individual having a disorder, includes several *in vivo* methods not included in the other methods (group VIII). For these reasons, the methods are considered distinct from each other and from the remaining Groups I-IV & VI, and require restriction. The searches for these methods are sufficiently different

from one another, that they would not be co-extensive and are burdensome to the examiner.

DISTINCTIONS BETWEEN GROUPS IX-XVIII

The distinctions between groups IX-XVIII exactly parallel the distinctions presented above between groups I-VIII, so the arguments will not be repeated, to avoid redundancy.

RESTRICTION CONCLUSION

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, or divergent subject matter, or the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if

the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

R sponse Requirement

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Multiple Inventors

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Examiner Contact Information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave Nguyen** can be reached on **571-272-0731**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Art Unit 1633

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER